K012098

SEP 2 0 2001

Attachment 4

510(k) Premarket Notification

PRECLUDE® Pericardial Membrane

Premarket Notification 510(k) Summary

A. Submitted By: W.L. Gore & Associates, Inc.
P.O. Box 500
Flagstaff, AZ 86002-0500

Date Prepared: September 17, 2001

Contact: R. Larry Pratt

Phone: 928-779-2771

B. Device Name: PRECLUDE® Pericardial Membrane

C. Applicant Device Description:

Biocompatible, expanded polytetrafluoroethylene (ePTFE). The ePTFE material has a nominal pore size of < 1 µm. The device is in sheet configuration with a variety of width and length dimensions.

D. Predicate Device:

The currently marketed PRECLUDE® Pericardial Membrane is cited as the predicate device which has been found to be substantially equivalent through the premarket notification process.

E. Applicant Device Labeling:

Like the predicate device, the applicant device is indicated for the reconstruction or repair of the pericardium. The indication statement for the predicate device is not changed as a result of this submission's clearance.

The WARNINGS section and the PRECAUTIONS section of the Instructions For Use are modified to provide special care

information for when the device is employed as a protective membrane and physical barrier to limit tissue attachment to the membrane and thus to the surface of a temporary mechanical circulatory assist device.

F. Technological Characteristics:

This premarket notification represents a modification to the labeling only. The technological characteristics of the predicate device are not changed. The applicant device is manufactured using the same inert, biocompatible ePTFE material as the predicate device, consequently bench testing was not performed.

Reports of data from animal studies and from clinical experiences documented in the literature demonstrate that ePTFE material with a nominal pore size of < 1 µm limits tissue to membrane attachment and thus attachment between surfaces that it covers and surrounding tissue.

G. Safety and Effectiveness Conclusions:

This submission represents only a modification to the WARNINGS section and the PRECAUTIONS section of the Instructions For Use for the currently marketed predicate device. Therefore, the similarities between the applicant and predicate device are numerous. These equivalencies combine to justify a substantially equivalent determination.

The only difference from the predicate device to the applicant device is that the WARNINGS section and the PRECAUTIONS section of the Instructions For Use for the applicant device provides special care information for when the device is employed as a protective membrane and physical barrier to limit tissue attachment to the membrane and thus to the surface of a mechanical circulatory assist device. This difference does not adversely affect the safety, integrity, therapeutic effect or functional characteristics of the applicant device when compared to the predicate device.

No new types of safety and effectiveness questions are raised by the applicant device when compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 0 2001

Mr. R. Larry Pratt
Regulatory Affairs
W. L. Gore and Associates, Inc.
Medical Products Division
3750 West Kiltie Lane
Flagstaff, AZ 86002

Re: K012098
Trade Name: PRECLUDE® Pericardial Membrane
Regulation Number: 21 CFR 870.3470
Regulation Name: Intracardiac Patch or Pledget Made of Polypropylene, Polyethylene Terephthalate, or Polytetrafluoroethylene
Regulatory Class: Class II (two)
Product Code: DXZ
Dated: September 17, 2001
Received: September 18, 2001

Dear Mr. Pratt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012098

Device Name: PRECLUDE® Pericardial Membrane

Indications For Use:

For reconstruction and repair of the pericardium

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012098

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)